IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

SANDRA ANN SMITH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	1:20CV212
	)	
ETHICON, INC. et al.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

LORETTA C. BIGGS, District Judge.

Plaintiff Sandra Ann Smith initiated this case as part of the multidistrict litigation in the Southern District of West Virginia concerning pelvic mesh devices attributable to Defendants Ethicon, Inc. and Johnson & Johnson. (ECF No. 1.) Discovery was completed during the MDL proceedings, and the case has since been referred to this Court for trial.

The number of live claims has been narrowed considerably. Plaintiff initially pleaded seventeen separate causes of action sounding in negligence, strict liability, and fraud. (*See id* ¶ 13.) However, after Defendants moved for partial summary judgment, (*see* ECF No. 20), Plaintiff voluntarily abandoned nearly all of her claims, (*see* ECF No. 49 at 2).[1] Of those claims

[1] Specifically, Plaintiff has relinquished the following claims: negligent manufacturing (part of Count I); strict liability–defective manufacturing (Count II); strict liability–failure to warn (Count III); strict liability–defective product (Count IV); strict liability–design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); unjust enrichment (Count XV); and discovery rule and tolling (Count XVIII). (*See id.*; ECF No. 29-1.) Those claims will be formally dismissed in the Order accompanying this Memorandum.

remaining—negligent failure to warn and negligent design defect (both part of Count I), as well as punitive damages (Count XVII)—the motion for partial summary judgment presently before the Court addresses just one: negligent failure to warn. (*See* ECF No. 21 at 6–8.) As explained below, the Court finds that Defendants are not entitled to summary judgment on that claim. Accordingly, the instant motion will be granted in part and denied in part.

I. LEGAL STANDARD

Summary judgment is appropriate when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is "genuine" if the evidence would permit a reasonable jury to find for the nonmoving party, and "[a] fact is material if it might affect the outcome" of the litigation. *Jacobs v. N.C. Admin. Office of the Courts*, 780 F.3d 562, 568 (4th Cir. 2015). When reviewing a motion for summary judgment, the role of the court is not "to weigh the evidence and determine the truth of the matter," but rather "to determine whether there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). To that end, the court must "resolve all factual disputes and any competing, rational inferences in the light most favorable" to the nonmoving party. *Rossignol v. Voorhaar*, 316 F.3d 516, 523 (4th Cir. 2003) (quoting *Wightman v. Springfield Terminal Ry. Co.*, 100 F.3d 228, 230 (1st Cir. 1996)).

II. DISCUSSION

Defendants manufactured and sold a pelvic mesh device called the TVT-Obturator ("TVT-O"). (ECF No. 29-1 ¶¶ 17, 19.) Plaintiff underwent the implantation of a TVT-O in May of 2013 in order to treat her stress urinary incontinence. (ECF No. 22-2 at 3.) After the surgery, however, Plaintiff began to experience a number of new medical problems—back,

leg, and pelvic pain and regular infections, among others. (ECF No. 22-4 at 4.) According to Plaintiff, "there is no other medical explanation" for these ailments aside from "Defendants' defective TVT-O." (ECF No. 23 at 3.)

As is relevant here, Plaintiff alleges that Defendants failed to adequately warn healthcare providers, including her own surgeon, about certain risks associated with TVT-O implantation. (*See* ECF No. 29-1 ¶ 91(f).) Under North Carolina law,[2] "[n]o manufacturer or seller of a product shall be held liable . . . for a claim based upon inadequate warning or instruction" unless three elements are satisfied. *See* N.C. Gen. Stat. § 99B-5(a). First, it must be shown that the defendant "acted unreasonably in failing to provide such warning or instruction." *Id.* Second, the lack of adequate warning must have been "a proximate cause of the harm for which damages are sought." *Id.* Third, the defendant must have known (or should have known) that, absent a warning, its product posed a "substantial risk of harm to a reasonably foreseeable user or consumer." *See id.* In the instant motion for partial summary judgment, Defendants focus on the second element—causation—only. (ECF No. 21 at 6–8.)

North Carolina applies the learned intermediary doctrine in failure-to-warn cases involving prescription drugs. Pursuant to N.C. Gen. Stat. § 99B-5(c), a manufacturer or seller that has given adequate warning of a drug's risks to a prescribing physician cannot be held

[2] In cases filed directly in the MDL, "the choice of law that applies is the place where the plaintiff was implanted with the product." *See Belanger v. Ethicon, Inc.*, No. 2:13-cv-12036, 2014 WL 346717, at *7 (S.D. W. Va. Jan. 30, 2014). In this case, that place is North Carolina. (*See* ECF No. 22-2 at 3.) "In tort actions, North Carolina courts adhere to the rule of lex loci and apply the substantive laws of the state in which the injuries were sustained." *Johnson v. Holiday Inn of Am.*, 895 F. Supp. 97, 98 (M.D.N.C. 1995); *Boudreau v. Baughman*, 368 S.E.2d 849, 854 (N.C. 1988) ("This Court has consistently adhered to the lex loci rule in tort actions."). Plaintiff is only seeking damages for injuries allegedly resulting from her surgery. Accordingly, the Court applies North Carolina's substantive law to her tort claims.

liable for failing to warn a consumer directly. *See* N.C. Gen. Stat. § 99B-5(c). Although the North Carolina Supreme Court has not spoken on whether the limitation on pharmaceutical liability outlined in § 99B-5(c) likewise extends to medical devices like the TVT-O, several federal courts—including the MDL court previously handling this case—have presumed that it does. *See, e.g.*, *Justus v. Ethicon, Inc.*, No. No. 2:12-cv-00956, 2016 WL 7404712, at *3 (S.D. W. Va. Dec. 21, 2016); *Carlson v. Bos. Sci. Corp.*, Nos. 5:15CV57–RLV, 3:15CV211–RLV, 2015 WL 5732107, at *2 (W.D.N.C. Sept. 30, 2015); *Baraukas v. Danek Med. Inc.*, No. 6:97CV00613, 2000 WL 223508, at *4 (M.D.N.C. Jan. 13, 2000).

In their lone argument for dismissing Plaintiff's negligent-failure-to-warn claim, Defendants contend that Plaintiff cannot establish that the alleged failure to warn proximately caused her injuries because her surgeon, Dr. Stephen Szabo, would not have changed his decision to prescribe a TVT-O even if he had been sufficiently warned of the device's risks. (*See* ECF No. 21 at 8.) Dr. Szabo's deposition testimony is somewhat inconsistent on this point. Defendants highlight portions of the deposition in which Dr. Szabo stated that, despite having since learned about the risks, he would still "use [a TVT-O] again now." (*See* ECF No. 20-1 at 44.) However, Dr. Szabo also said that, had he been warned that TVT-O implantation could produce serious complications, he would have altered the risk-benefit discussions he had about the device with his patients, including Plaintiff, to include that information. (*See id.* at 38–39.) In addition, Plaintiff has testified unequivocally that she would not have elected to have the surgery if Dr. Szabo had discussed the full range of risks with her. (*See id.* at 95–96.)

Thus, the record evidence shows the following: (1) had he been warned of the risks, Dr. Szabo might still have recommended a course of treatment to Plaintiff which included

TVT-O implantation; however, (2) he would not have done so without advising Plaintiff that severe complications could result; and (3) had she been so advised, Plaintiff would have foregone the operation. On these facts, a reasonable jury could find that Defendants' failure to warn Dr. Szabo proximately caused Plaintiff's injuries. Accordingly, Defendants are not entitled to judgment as a matter of law on Plaintiff's negligent-failure-to-warn claim.

For these reasons, the Court enters the following:

ORDER

IT IS THEREFORE ORDERED that Defendants' Motion for Partial Summary Judgment, (ECF No. 20), is GRANTED IN PART AND DENIED IN PART.

The motion is GRANTED with respect to the abandoned claims listed in footnote one of the Memorandum accompanying this Order. Those claims are hereby DISMISSED WITH PREJUDICE.

The motion is DENIED with respect to Plaintiff's negligent-failure-to-warn claim.

This, the 16th day of June 2020.

/s/Loretta C. Biggs
United States District Judge